REMARKS

In response to the Office Action dated October 16, 2007, the Applicant respectfully requests entry of the above amendments and consideration of the following remarks.

Claims 16-24, 38 and 39 are pending in the current application. Claims 1-15 and 25-37 have been canceled without prejudice to the subject matter contained therein.

Claim 17 was rejected under 35 USC 112, second paragraph, because of the language "radially expanding a tissue dilatation means." The Applicant respectfully submits that this language refers to means for dilatating tissue, such as balloon 24 or mesh structure 104. In any event, the cited language is no longer in the claims on account of the above amendments, so the rejection is believed now to be moot.

Claims 16-24 were rejected under 35 USC 102(e), with the Examiner citing U.S. Patent No. 5,611,775 to Machold et al. ("Machold"). In response to this rejection, the Applicant respectfully submits the following remarks.

Claim 16, as amended above, recites the steps of providing a catheter having a flexible treatment sheath and a dilatation balloon within the flexible treatment sheath, "wherein the flexible treatment sheath is formed of an elastic material and the dilatation balloon is formed of a substantially inelastic material;" intraluminally advancing the catheter until the flexible treatment sheath is adjacent a predetermined treatment site; supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, "to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site," and while maintaining the treatment sheath in said intimate and substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon within the compartment to effect a dilatation of the surrounding tissue. New claim 38 adds that the treatment sheath "is formed of a biocompatible elastomeric material consisting essentially of at least one of the following: latex, urethane, silicone, and a thermoplastic elastomer." New claim 39 adds that "the biocompatible elastomeric material has a modulus of elasticity in the range of 2,000 to 80,000 psi, said sheath has a uniform thickness in the range of 0.5-5 mils, whereby the treatment sheath elastically expands into said substantially conforming contact."

Support for the claim amendments and new claims can be found throughout the original disclosure. For example, with respect to the treatment sheath, the specification states:

> The [treatment] sheath is elastically expandable radially into a substantially conforming contact with surrounding tissue at the treatment site.
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> Thus in accordance with the present invention, the likelihood of restenosis is significantly reduced due to administration of therapeutic agents through an elastic membrane held in intimate, conforming contact with the tissue under treatment.
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> Because of the elasticity of sheath 22, it does not enlarge the artery or otherwise substantially change the shape of the surrounding tissue. Rather, it conforms to the shape and contours of the vessel wall, as seen in FIG. 5.
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> [A] wall segment 86 of sheath 22 (FIG. 9) is highly flexible. Wall segment 86 does not tend to flatten or otherwise deform nodules 82. Rather, the wall portion segment elastically elongates … .
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> * * *
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> The therapeutic agent is delivered by perfusion through a delivery balloon or membrane formed of a highly elastic material and mounted independently of the dilatation structure.

(Specification, paras. 13, 28, 52, 58, 72 (emphasis added)).

With respect to the specific materials that can be used for various embodiments of the treatment sheath as recited in dependent claims 38 and 39, the specification states:

> The sheath advantageously is formed of a biocompatible elastomer having a modulus of elasticity in the range of about 2,000 to 80,000 psi, and with a uniform thickness in the range of about 0.5-5 mils. Accordingly, responsive to a low inflation pressure (e.g. about one atmosphere gauge pressure), the sheath readily expands into the desired intimate and conforming contact with tissue. The elasticity is a positive factor in permitting the sheath to stretch in response to encountering tissue surface irregularities.
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> * * *
>
> Delivery sheath 22 is formed of an elastic biocompatible polymer,

> e.g. latex. Other suitable materials include polyurethane, silicone, and thermoplastic elastomers. The thickness of the sheath is determined in view of the selected material, to provide a high degree of stretching of the sheath to conform to the shape and contours of surrounding tissue when sheath 22 is expanded against the tissue. In general, the ability of the sheath to conform to tissue irregularities is a function of the material modulus of elasticity and sheath thickness. Consistent with an adequate tensile strength, lower elastic moduli are preferred. A sheath having a lower modulus of elasticity experiences a greater amount of elastic elongation or "stretch" in response to a given force, i.e. a given fluid pressure of the therapeutic agent in the compartment. In particular, suitable materials will have elastic moduli within a range from about 2,000 psi to about 80,000 psi. Preferred thicknesses are in the range of from about 0.5 mils to about 5 mils.

(Specification, paras. 15, 47 (emphasis added)).

In contrast to the "elastic" treatment sheath, the dilatation balloon inside the sheath is "substantially inelastic," giving it a "non-distensible" property whereby it tends to maintain its shape under increased internal pressure. The specification states:

> Preferably the delivery means comprises an elongate and flexible catheter, with the dilatation means comprising a substantially inelastic and fluid impermeable dilatation balloon.
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> * * *
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> Dilatation balloon 24 preferably is constructed of a polymeric material that is sufficiently pliable or formable to readily achieve an enlarged state, yet is relatively non-distensible, i.e. tending to maintain it shape under increased fluid pressure within the balloon. Nylon is a preferred material for the dilatation balloon. Other suitable materials include PET, polyolefin, polyethylene, polybutylene terepthalate, PVC, polypropylene and their copolymers.

(Specification, paras. 14, 45 (emphasis added)).

As set forth in the specification, these material properties are important to the intended purpose and operation of the invention:

> Several performance advantages arise from the greater elasticity [of the treatment sheath] and resulting conformity to the tissue. First, wall segment 86 and the arterial tissues are contiguous over a much greater surface area. As a result a fluid tight seal is formed

> over the sheath/tissue interface, preventing blood from contacting tissue that is contiguous with the sheath. The prevention of contact with blood, particularly as to freshly cracked lesions, may considerably reduce the probability of restenosis.
>
> Second, the seal enhances concentration of the therapeutic agent along the interface, more specifically that portion of the sheath/tissue interface where pores 56 are formed through the sheath. Improved concentration reduces the amount of the agent needed for effective treatment, and reduces potential toxicity concerns.
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> Third, the fluid tight seal effectively isolates the therapeutic agent and blood from one another, preventing the loss of efficacy in certain agents caused by contact with blood.
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> With the delivery sheath and tissue contiguous over a much greater proportion of their interface as in FIG. 9, the therapeutic agent perfuses through pores 56 directly into tissue, as opposed to merely perfusing into gaps between the balloon and tissue as would be the case in FIG. 8. The result is a more uniform application of the therapeutic agent to tissue under treatment. Finally, on a larger scale than that depicted in FIGS. 8 and 9, the elastic delivery sheath can conform to non-cylindrical arterial passageways, for example in regions of the coronary artery with collateral arteries, branching or eccentric lesions. The highly flexible delivery sheath can establish fluid tight seals in such areas, where the conventional non-distensible balloon does not "fit".

(Specification, paras. 59-62 (emphasis added)).

The Machold Device

In contrast to Applicant's invention, the Machold device has a configuration that is the opposite of Applicant's "elastic" outer treatment sheath and substantially "inelastic" inner dilatation balloon. Machold's outer member is inelastic, and its inner member is elastic. Machold states:

> The inner inflatable member 16, which is preferably formed of material exhibiting elastic expansion, inflates, expanding the outer inflatable member 19.
>
> * * *

> The inner inflatable member may be formed from latex or an elastomer or an olefinic ionomer such as Surlyn® sold by E. I. duPont, deNemours & Co. which is elasticly expandable up to a first pressure level and is relatively non-compliant at pressures above the first level.
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> * * *
>
> The outer inflatable member may be formed from conventional inelastic dilatation balloon materials such as polyvinyl chloride, polyethylene, polyethylene terephthalate and the olefinic ionomers described above.

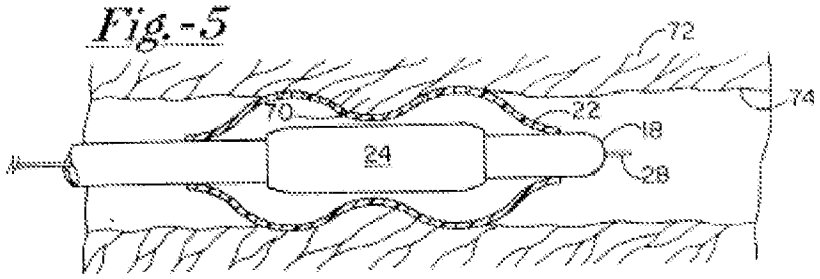
(Machold, 5:56-59, 6:32-37, 6:43-46 (emphasis added)).

The Claims as Compared to Machold

The Applicant respectfully submits that the pending claims are neither anticipated nor rendered obvious by Machold or any of the other prior art of record.

Claim16 recites that the outer treatment sheath is formed of an "elastic" material and that the inner dilatation balloon within the treatment sheath is formed of a substantially "inelastic" material." By contrast, Machold discloses the opposite, with the inner inflatable member exhibiting "elastic" expansion, and the outer inflatable member formed from "inelastic" materials. (Machold, 5:56-59, 6:32-37, 6:43-46).

The Applicant's arrangement provides advantages not achieved by the Machold device. Because of Applicant's "elastic" outer treatment sheath, the outer treatment sheath is expandable radially into a substantially conforming contact with surrounding tissue at the treatment site. This is illustrated in Applicant's FIG. 5, reproduced below:



Because Machold does not have an elastic outer sheath, it does not perform in this manner.

In addition, Applicant's substantially "inelastic" inner dilatation balloon provides the advantage that it can press the tissue into the shape of the balloon, which is illustrated in Applicant's FIG. 6. The inner balloon is "relatively non-distensible, i.e. tending to maintain it shape under increased fluid pressure within the balloon." (Specification, para. 45 (emphasis added)). This substantially "inelastic" inner balloon cooperates with the "elastic" outer treatment sheath to achieve the unique functioning described in the Applicant's specification and illustrated in the Applicant's figures.

The Applicant also respectfully submits that the claimed invention is not rendered obvious by Machold, either alone or in combination with any other prior art of record. Machold specifically states that its inner member should be "elastic" and its outer member "inelastic." Nothing in Machold or any other reference suggests altering the properties of the Machold device to cause it to operate in an opposite manner to the way Machold describes. Simply put, there is no "reason" provided in the prior art or elsewhere as to why a person of ordinary skill in the art would have sought to modify Machold contrary to its teachings in order to arrive at a device that functions as Applicant has taught. See KSR v. Teleflex, 550 U.S. 1 (2007).

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In view of the foregoing, the Applicant respectfully requests favorable reconsideration of this application and allowance of all claims. Should any questions arise, the Examiner is invited to call the undersigned at the number given below. The Commissioner is hereby authorized to charge any fees and credit any overpayments associated with this filing to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,

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